Best Practices in Anticoagulant Therapy Webinar - Part 2: Preparing for new Joint Commission EPs effective July 1

9-10 am (PT)
10-11 am (MT)
11 am-12 pm (CT)
12-1 pm (ET)
Best Practices in Anticoagulant Therapy Webinar - Part 2:
Preparing for new Joint Commission EPs effective July 1

Webinar Audio – Information & Tips

• Audio is by VOIP only – use your computer speakers or headphones to listen
• There are no dial in lines
• If you hear background music, you have more than one window open. Close the “test” window & music will stop.
• If you currently cannot hear audio, click the “play” icon in the upper left pane to launch audio
• Participants are connected in listen-only mode
• Feedback or dropped audio are common for live streaming events, and are localized issues. Refresh your screen or rejoin the event if this occurs.
Eight new Anticoagulant Therapy elements of performance (EPs) have been added to the National Patient Safety Goals (NPSG.03.05.01)

These EPs are effective July 1, 2019 for all Joint Commission-accredited hospitals, critical access hospitals, nursing care centers, and medical centers (accredited under the ambulatory health care program)

This two-part webinar series provides information about best practices and assists customers in answering questions before the July 1 effective date
This session seeks to:

- Share best practices in anticoagulant therapy
- Assist healthcare organizations to better understand and implement the new EPs
- Answer participant questions about the new Anticoagulant Therapy elements of performance during the live session
Best Practices in Anticoagulant Therapy Webinar - Part 2: Preparing for new Joint Commission EPs effective July 1

About Our Presenters

Anticoagulation Forum Content Experts:
Jack E. Ansell, MD, MACP
and
Allison Burnett, PharmD, CACP, PhC
Best Practices in Anticoagulant Therapy Webinar - Part 2:
Preparing for new Joint Commission EPs effective July 1

Slides are available for download now!

- To access the slides, see the Event Resources Pane
- Select the slides for today’s session
- A new window will open where you can download and save or print the PDFs
Housekeeping Information

- Ask questions through the Questions pane
- Visit any links or resources provided in the slides
- Download the slides
- When available, share the recording
- If you experience audio issues, see slide 2 for tips to resolve
Within two weeks, the webinar recording and slide deck will be accessible on The Joint Commission website via the Anticoagulant Therapy Webinar Series landing page at:

https://www.jointcommission.org/anticoagulant_therapy_webinar_series/

Anticoagulant Therapy Webinar Series
April 8, 2019

Best Practices in Anticoagulant Therapy Webinars – Part 1 and Part 2

Eight new Anticoagulant Therapy elements of performance (EPs) within the National Patient Safety Goal (NPSG) 03.05.01 go into effect on July 1, 2019 for all Joint Commission-accredited hospitals, critical access hospitals, nursing care centers, and medical centers (accredited under the ambulatory health care program). A rise in adverse drug events associated with direct oral anticoagulants (DOACs) led The Joint Commission to update this NPSG to address DOACs and help to reverse that trend. The Joint Commission and the Anticoagulation Forum developed a two-part webinar series to share best practices and answer questions about implementation.

Anticoagulation therapy remains a commonly prescribed and used class of drugs, but it is also a leading cause of avoidable severe medication-related adverse events. This webinar series will address each EP and provide insights on implementation within health care settings to successfully achieve established targets.

The sessions aim to:

- Share best practices in anticoagulant therapy
- Assist health care organizations to better understand and implement the new EPs
- Answer participant questions about the new Anticoagulant Therapy elements of performance during the live session
Disclosure Statement

These staff and speakers have disclosed that neither they nor their spouses/partners have any financial arrangements or affiliations with corporate organizations that either provide educational grants to this program or may be referenced in this activity:

- Andrew Bland, MD, MBA, MSPA, FAAP, FACP, Medical Director, The Joint Commission
- Jack E. Ansell, MD, MACP
- Allison Burnett, PharmD, CACP, PhC
How Can I Achieve & Surpass the National Patient Safety Goals? (Part 2)

Tuesday, May 7, 2019

Speakers:
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Allison Burnett, PharmD

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Scott Kaatz, DO, MSc
Tracy Minichiello, MD
Why Anticoagulants?

Of the 16 NPSGs, 3 apply to medicines
Of these 3, 1 applies specifically to anticoagulants

- For outpatients, anticoagulants (AC) consistently rank as the class of medications most frequently leading to emergency room visits and hospital admissions for adverse drug events (ADEs).[1-3]
- Warfarin is implicated in:
  - Approximately 32% of emergency visits for ADEs in the elderly
  - 50% of which result in hospitalization.[3]
- In 2010, a new class of AC potentially better and safer than warfarin (Direct Oral Anticoagulants or DOACs) entered the market

Comparing DOACs to Warfarin

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Warfarin</th>
<th>DOAC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Onset of action</td>
<td>Slow</td>
<td>Rapid</td>
</tr>
<tr>
<td>Half-life</td>
<td>Long</td>
<td>Short</td>
</tr>
<tr>
<td>Dosing</td>
<td>Variable</td>
<td>Fixed</td>
</tr>
<tr>
<td>Food effect</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Drug interactions</td>
<td>Many</td>
<td>Few</td>
</tr>
<tr>
<td>Measuring Required</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Antidote</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

- Severe complications from DOACs do exist
- Between 2013 and 2014, rivaroxaban and dabigatran were the 5th and 10th most common drugs for adverse drug reactions (ADE) related emergency room visits in older adults
- This reflects the increased use of DOACs and their potential for toxicity.[1]
- Many of these events can be prevented

Anticoagulants Are Also a Common Cause of Inpatient ADE

Inpatients are treated with IV unfractionated heparin (UFH) and low molecular weight heparin (LMWH) in addition to warfarin and DOACs

- 4% of inpatients experience major bleeding with IV UFH[1]
- Heparin-related bleeding can be significantly reduced by systematically applying a nomogram for dosing[2]
- Bleeding rates of 1.8% and 1.1% with LMWH and Fondaparinux in a 40,000 inpatient analysis[3]
- 18.7% of 20,687 inpatients received an excess dose of LMWH for myocardial infarction → significantly associated with major bleeding (OR 1.43) and death (OR 1.35) vs those who received correct dose

The Joint Commission Has Revised Anticoagulation-Related Safety Goals

• 6 new or revised Elements of Performance (EP)
• 2 EPs unchanged (# 7 and 8)
• Applicable to:
  – Acute Care Hospitals
  – Critical Access Hospitals
  – Nursing Care Centers
  – Medical Centers (accredited under Ambulatory Health Care Programs)
The First 3 EPs
Discussed April 2

1. Use approved protocols and evidence-based guidelines for initiation/maintenance of therapy

2. Use approved protocols and evidence-based guidelines for reversal of AC and management of bleeding for each medication

3. Use approved protocols and evidence-based guidelines for perioperative management of all patients on oral anticoagulants
EP-4: The [hospital/organization] has a written policy addressing the need for baseline and ongoing laboratory tests to monitor and adjust anticoagulant therapy. [https://www.jointcommission.org/standards_information/npsgs.aspx](https://www.jointcommission.org/standards_information/npsgs.aspx)
NPSG EP - 4

Have a written policy to address the need for baseline and ongoing laboratory tests to monitor and adjust therapy

Why was this chosen?

• Unlike warfarin, there is often a lack of coordinated care for DOACs

• **Baseline labs** needed for all anticoagulants to:
  – Identify issues that may preclude use of anticoagulants
  – Aid in selection of most appropriate anticoagulant regimen
  – Provide initial lab values that should be trended over time

• **Ongoing laboratory monitoring** of anticoagulant activity:
  – Required for warfarin (Coumadin) via the INR due to narrow therapeutic index and wide variability
  – NOT required for DOACs due to predictable dose response but may be indicated in certain circumstances

NPSG EP - 4

Have a written policy to address the need for baseline and ongoing laboratory tests to monitor and adjust therapy

- **Baseline labs for all anticoagulants**
  - Hemoglobin, hematocrit, platelets
  - aPTT, PT/INR, maybe anti-Xa
  - Renal function
  - Liver function as needed based on clinical history

- **Ongoing labs for conventional anticoagulants:**
  - Anticoagulant activity: IV unfractionated heparin, warfarin
  - Renal function, CBC: LMWH, fondaparinux

- **Periodic monitoring of DOACs**
  - CBC, renal and hepatic function
  - Every 3-6 months (more or less frequent depending on health status)

Ordering and assessment of these labs should be embedded in workflow to avoid patient harm and to optimize therapy
NPSG EP - 4

Have a written policy to address the need for baseline and ongoing laboratory tests to monitor and adjust therapy

- **Measurement** of DOACs may be recommended under specific circumstances

  - Which test to measure DOACs is controversial

  - Literature shows excessive and inappropriate measuring for DOACs resulting in excessive use of resources\(^1\)

  - Guidelines provide recommendations for when to measure and with which specific assay

Example of Resource Information

When should DOACs be measured?

Guidance for the practical management of the direct oral anticoagulants (DOACS) in VTE…

**Table 7** Potential indications for DOAC measurement [38–40]

<table>
<thead>
<tr>
<th>Detection of clinically relevant levels</th>
<th>Detection of expected on-therapy levels</th>
<th>Detection of excessive levels</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urgent or emergent invasive procedure</td>
<td>Assessing adherence</td>
<td>Hemorrhage</td>
</tr>
<tr>
<td>Neuraxial anesthesia</td>
<td>Breakthrough thrombosis</td>
<td>Diminished/changing renal function</td>
</tr>
<tr>
<td>Major trauma</td>
<td></td>
<td>Hepatic impairment</td>
</tr>
<tr>
<td>Potential thrombolysis in acute thromboembolism</td>
<td></td>
<td>Accidental or intended overdose</td>
</tr>
<tr>
<td>Hemorrhage</td>
<td></td>
<td>Drug interactions</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Advanced age</td>
</tr>
</tbody>
</table>

**Guidance Statements from the Anticoagulation Forum:**

- Suggest clinicians do not routinely measure DOAC activity
- If indicated, suggest clinicians use validated, readily available assays
- Chosen assay should be suitable for the prescribed DOAC and indication for measurement

### What lab assay should be used for DOAC monitoring?

**Table 8** Suggestions for laboratory measurement of DOACs [40]

<table>
<thead>
<tr>
<th>Drug</th>
<th>Clinical objective</th>
<th>Test suggested</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dabigatran</td>
<td>Determine if clinically relevant below on-therapy drug levels are present</td>
<td>TT</td>
<td>Normal TT likely excludes clinically relevant drug levels</td>
</tr>
<tr>
<td></td>
<td>Estimate drug levels within on-therapy range</td>
<td>Suggested test</td>
<td>Interpretation</td>
</tr>
<tr>
<td></td>
<td>Determine if above on-therapy drug levels are present</td>
<td>Suggested test</td>
<td>Interpretation</td>
</tr>
<tr>
<td>Rivaroxaban</td>
<td>Anti-Xa</td>
<td>Normal anti-Xa activity likely excludes clinically relevant drug levels</td>
<td>Anti-Xa</td>
</tr>
<tr>
<td>Apixaban</td>
<td>Anti-Xa</td>
<td>Normal anti-Xa activity likely excludes clinically relevant drug levels</td>
<td>Anti-Xa</td>
</tr>
<tr>
<td>Edoxaban</td>
<td>Anti-Xa</td>
<td>Normal anti-Xa activity likely excludes clinically relevant drug levels</td>
<td>Anti-Xa</td>
</tr>
</tbody>
</table>


Example of Resource Information

American Society of Hematology (ASH) VTE Guidelines

- Panel *suggests against* using anti–factor Xa concentration monitoring to guide LMWH dose adjustment in:
  - Patients with *renal dysfunction* (creatinine clearance <30 mL/min) receiving LMWH therapy for treatment of VTE
  - Patients with *obesity* receiving LMWH therapy for treatment of VTE

- For patients receiving DOAC therapy for VTE, the ASH guideline panel *suggests against* measuring DOAC anticoagulant effect during management of bleeding

Example of Resource Information

**Inpatient Antithrombotic Management**

<table>
<thead>
<tr>
<th>Patient Age Group</th>
<th>Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>( ) N/A</td>
<td>( ) Adult</td>
</tr>
<tr>
<td>(X) All Ages</td>
<td>( ) Pediatric</td>
</tr>
<tr>
<td>( ) Newborns</td>
<td></td>
</tr>
</tbody>
</table>

**DESCRIPTION/OVERVIEW**

- The purpose of this procedure is to describe inpatient antithrombosis management systems, processes and resources available at University of New Mexico Hospital (UNMH), as well as delineating the roles and responsibilities.
- These practices are in accordance with regulatory bodies such as the Joint Commission, Medicaid Services (CMS), and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).
- This procedure pertains to all inpatients, except as detailed in this document.
- Any dosing information that is contained within this document is for educational purposes only and may be performed under the authority of a licensed healthcare professional.
- The procedures for antithrombotic patients are detailed in this document.
- An individual patient’s clinical status may require individualization of the practices described in this document.

3. **Required baseline and maintenance laboratory information for anticoagulant medication orders**

   When an initial order for any anticoagulant medication is received, pharmacists should review the chart for relevant baseline patient information prior to dispensing any doses whenever possible. This baseline information includes, but is not limited to:
   
   i. Age
   ii. Weight
   iii. Serum creatinine
   iv. Current coagulation parameters, such as INR and complete blood count.

   b. Ongoing assessment of relevant, current laboratory values for longitudinal management of patients should be ensured by pharmacists. These labs may include, but are not limited to, INR, serum creatinine, complete blood count, anti-Factor Xa level, and aPTT.

   c. If this laboratory information is not available, pharmacists have the authority of the UNMH Pharmacy and Therapeutics (P&T) Committee to order labs as needed to ensure timely, optimal management of these patients.

   d. Labs results are automatically documented in the electronic health record (EHR) and are reviewed by pharmacists and the primary medical or surgical service when making therapy decisions.

4. **Therapeutic antithrombosis monitoring and management**

   a. In addition to pharmacist review of antithrombotics upon order entry, pharmacists also use available tools (e.g., Explorer reports, mPage dashboards in the EHR) to identify and review...
Where do I find them?

Sample resources can be found at the Anticoagulation Centers of Excellence:
https://acforum-excellence.org/
Where do I find them?

- And more . . .
NPSG EP – 5

• Address AC safety practices by identifying, responding to and reporting ADEs; and evaluating and improving safety practices and measuring the effectiveness of actions

EP-5: The [hospital/organization] addresses anticoagulation practices through the following: Establishing a process to identify, respond to, and report adverse drug events, including adverse drug event outcomes; Evaluating anticoagulation safety practices, taking actions to improve safety practices, and measuring the effectiveness of those actions in a time frame determined by the organization https://www.jointcommission.org/standards_information/npsgs.aspx
NPSG EP - 5

Address AC safety practices by identifying, responding to and reporting ADEs; and evaluating and improving safety practices and measuring the effectiveness of actions.

Why was this chosen?

- Identification of common, preventable, and measurable healthcare-associated anticoagulant ADEs is a key component of quality improvement efforts to:
  - Drive prevention
  - Benchmark progress
  - Promote a culture of anticoagulation safety
NPSG EP - 5

Address AC safety practices by identifying, responding to and reporting ADEs; and evaluating and improving safety practices and measuring the effectiveness of actions.

- No prescribed metric(s) that must be measured
- Many healthcare entities align EP-5 with pre-existing efforts
  - ADE reporting systems
  - Medication safety subcommittee
  - Hospital Improvement Innovation Network (HIIN) INR >5
  - Time in therapeutic range (TTR)
  - Hospital-acquired VTE (VTE-6, PSI-12)
- Other approaches
  - Bleeding & thrombotic events (use of antidotes, coding, clinic software)
  - Rates of appropriate/inappropriate DOAC prescribing
  - De-escalation of combined therapy (e.g., concomitant aspirin)
  - Antidote stewardship
  - Transitions of care (referrals, follow-up appointments, etc.)
  - Anticoagulation stewardship programs
Example of Resource Information
Pharmacist-led DOAC Screening Service

Table 1. Patient Contact and Interventions.

<table>
<thead>
<tr>
<th></th>
<th>Number of Successful Phone Follow-Ups</th>
<th>Number of Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>New</td>
<td>125 (125/317 = 39.4%)</td>
<td>79 (79/317 = 25%)</td>
</tr>
<tr>
<td>Refill</td>
<td>59 (59/595 = 9.9%)</td>
<td>86 (86/595 = 14.5%)</td>
</tr>
</tbody>
</table>

Figure 1. Total number of new prescriptions screened from April 2016 to April 2017.

Figure 2. Total number of refill prescriptions screened April 2016 to April 2017.

Table 2. Drug Interactions Requiring Intervention.

New
- Carbamazepine (2)
- Phenytoin (4)
- Phenobarbital (1)
- Refill
- Carbamazepine (1), phenytoin (1), rifampin (1)

Where do I find them?
NPSG EP – 6

Educate patients and families about the anticoagulant, including: Adherence to dose and schedule; Importance of follow-up and laboratory testing (if applicable); Potential drug-drug and drug-food interactions and adverse drug reactions

EP-6: The [hospital/organization] provides education to patients and families specific to the anticoagulant medication prescribed, including the following: Adherence to medication dose and schedule; Importance of follow-up appointments and laboratory testing (if applicable); Potential drug-drug and drug-food interactions; The potential for adverse drug reactions

https://www.jointcommission.org/standards_information/npsgs.aspx
NPSG EP - 6

Educate patients and families about the anticoagulant, including: Adherence to dose and schedule; Importance of follow-up and laboratory testing (if applicable); Potential drug-drug and drug-food interactions and adverse drug reactions

Why was this chosen?

• Unlike warfarin, there is often a lack of coordinated care for DOACs
• Non-adherence places patients at risk for bleeding and/or clotting
• Patients need to be aware some foods and medicines interact with anticoagulants and increase risk of bleeding or clotting
• Actively engaged patients have better care experiences, improved outcomes and lower overall healthcare costs¹,²
• Patients and caregivers should be empowered to navigate and troubleshoot issues, so teach back with comprehension is important

Example of Resource Information

AC Forum Guidance statement(s):

• Suggest hospitals implement systematic anticoagulation management processes and services (inpatient and outpatient) for DOACs (and all anticoagulants)

• Documentation and processes should facilitate appropriate:
  • Patient and agent selection
  • Perioperative management
  • Switches between anticoagulants
  • Transitions between care settings

• Use of discharge checklist (for DOACs and other anticoagulants) strongly encouraged

Example of Resource Information


U.S. Department of Health and Human Services
Agency for Healthcare Research and Quality
540 Gaither Road
Rockville, MD 20850

Where do I find them?
NPSG EP – 7 & 8

• Use only oral unit-dose products, prefilled syringes or premixed infusion bags when available
• Use programmable pumps for heparin therapy

EP-7: The [hospital/organization] uses only oral unit-dose products, prefilled syringes, or premixed infusion bags when these types of products are available

EP-8: When heparin is administered intravenously and continuously, the [hospital/organization] uses programmable pumps to provide consistent and accurate dosing
End of Part Two

Take home messages:

• Know and understand the NPSGs as they apply to anticoagulants
• Administrative commitment of personnel and resources to meet NPSG
• Empower the appropriate personnel to formulate and carry out policies
• Develop institution-specific, evidence-based protocols or guidelines
• Systematically applied
• Follow up and measure performance
• Adjust as necessary
As easy as 1, 2, 3 . . .

Administrative commitment to EP goals, personnel and $ resources

Personnel develop policies & implement protocols based on evidence-based guidelines

Organization monitors and measures performance

Adjust as necessary

Re-apply
Best Practices in Anticoagulant Therapy Webinar - Part 2: Preparing for new Joint Commission EPs effective July 1

- Please ask questions through the Questions pane
- Click the arrow to expand and close the pane.
- Include slide reference numbers when possible
Questions

• All unanswered questions will be reviewed and a Q&A document posted online

• When the follow-up items from this session are posted, participants will receive an email
Resources

• NPSG Anticoagulant Therapy R3 Report | Requirement, Rationale, Reference
  https://www.jointcommission.org/assets/1/18/R3_19_Anticoagulant_therapy_FINAL2.PDF

• Anticoagulant Therapy Webinar Series Landing Page
  https://www.jointcommission.org/anticoagulant_therapy_webinar_series/

• Anticoagulation Centers of Excellence
  https://acforum-excellence.org/Resource-Center/

• ASH Clinical Guidelines

• MAQI2 Anticoagulation Toolkit
  http://www.anticoagulationtoolkit.org/

• University of Washington Anticoagulation Services
  http://depts.washington.edu/anticoag/home/
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- A new window will open permitting you to download and save or print the PDF.
Participants will receive an automated email with a link to the evaluation survey.

We use your feedback to inform future content and assess the quality of our sessions.
Thank you for attending this session.